



Vertex Pharmaceuticals (Canada) Incorporated
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VIA EMAIL: HESA@parl.gc.ca

November 6, 2020

MP Ron McKinnon, Chair
House of Commons Standing Committee on Health
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Re: HESA Study on the *Patented Medicines Guidelines*

Dear Mr. McKinnon:

On behalf of Vertex Pharmaceuticals (Canada) Incorporated ("Vertex"), thank you for the opportunity to provide input into the House of Commons Standing Committee on Health's study into the Patented Medicine Prices Review Board ("PMPRB") Guidelines. Please accept this letter as Vertex's input to your study. Our input herein should be considered complementary and supportive to submissions and presentations from BIOTEC Canada and RAREi (the Canadian Forum for Rare Disease Innovators).

Vertex continues to believe that **the amendments to the *Patented Medicines Regulations* ("the Regulations") may delay or stop new innovative medicines from launching in Canada.** We are already seeing fewer drug launches¹ and clinical trials² in Canada compared to previous years – this is tied directly to the uncertainty and dramatic price controls resulting from the amendments to the Regulations and the new PMPRB Guidelines.

Our primary concerns are centered around arbitrary price reductions and commercial uncertainty due to the broad powers given to the PMPRB through the Regulations.

- **The method of how innovation will be measured, and the associated mandatory discounts, are arbitrary and will not be evaluated by an independent third party or medical experts trained in evaluating evidence-based clinical information.** This process will trigger mandatory discounts for products, contributing to high levels of uncertainty for manufacturers.
- **Mandated market size-related price reductions of up to 65% create an unfavourable and uncertain market for new drug launches in Canada.** Mandated reductions of this type and scale for new patented medicines may delay or altogether stop the launch of new innovative medicines in Canada due to the uncertainty related to net prices.

We understand that managing drug affordability and accessibility within the Canadian healthcare system requires a delicate balancing act, but we believe that the Regulations as written skew in favor of affordability at the expense of accessibility.

¹ Rawson, Nigel. "Fewer New Drug Approvals in Canada: Early Indication of Unintended Consequences from New PMPRB Regs?" Canadian Health Policy, March 2020. <https://www.canadianhealthpolicy.com/products/fewer-new-drug-approvals-in-canada--early-indication-of-unintended-consequences-from-new-pmprb-regs-.html>

² Rawson, Nigel. "Clinical Trials in Canada Decrease: A Sign of Uncertainty Regarding Changes to the PMPRB?" April 2020. <https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html>



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By removing the economic factors from the Regulations and only implementing the new PMPRB11 basket of countries, it is anticipated that list prices will drop by more than 25%³. This is a substantial reduction in prices, bringing Canada well in line with comparable international markets without the same level of risk of reduced access to innovative medicines posed by the implementation of the economic factors. This would also provide innovators with improved commercial certainty when assessing Canada as a potential destination for launching future clinical trials and medicines.

We continue to have substantial concerns around the impact of these Regulations on future access to innovative medicines for rare diseases in Canada. **Vertex strongly urges the federal government to reconsider the factors as outlined above, to ensure that Canadians continue to have access to future innovative medicines.**

Sincerely,

Michael Siau
Country Manager
Vertex Pharmaceuticals (Canada) Incorporated

³ Canadian Association for Population Therapeutics. Managing risk to improve health outcomes: how to move population health forward in an era of uncertainty. <https://www.capt-actp.ca/wp-content/uploads/2020/10/Breakout-1.pdf>